

REMARKS

The Examiner rejected claims 1, 8, and 38-41, and stated that claims 11 and 12 are allowable. Claims 1 and 3-10 are amended herein to recite that the isolated nucleic acid molecule consists essentially of a nucleic acid sequence that is at least fifteen contiguous nucleotides of SEQ ID NO:6 or SEQ ID NO:1. Claim 38 is amended to recite that the isolated nucleic acid molecule is from 15 to 100 nucleotides in length. Support for these amendments can be found in Applicants' specification at, for example, page 8, lines 22-26, which disclose that a nucleic acid can be at least about 8 (e.g., 15) nucleotides in length. Thus, no new matter has been added.

In light of these amendments and the following remarks, Applicants respectfully request reconsideration and allowance of claims 1, 8, 11, 12, and 38-41. Applicants also request rejoinder and allowance of the non-elected species within claims 1, 3-7, 9, and 10.

Rejections under 35 U.S.C. §102

The examiner rejected claims 1, 8, and 38 under 35 U.S.C. §102(e) as allegedly being anticipated by U.S. Publication No. 2001/0053519 (the Fodor *et al.* publication). The Examiner asserted that the Fodor *et al.* publication teaches a complete set of n-mers that represents every possible combination of "n" nucleotides. Thus, the Examiner alleged that the Fodor *et al.* publication anticipates the variants recited in claims 1, 8, and 38, including the variant at position 298 of SEQ ID NO:6.

Applicants respectfully disagree. The Fodor *et al.* publication teaches that the genus of all possible 10-mer nucleic acids includes 1,048,576 distinct species of sequences. *See*, paragraph [0101] at page 10 of the Fodor *et al.* publication. The Fodor *et al.* publication, however, does not set forth any specific nucleic acid sequences. According to the MPEP, § 2131.02, a prior art genus does not necessarily anticipate a claim to a species within that genus. This section of the MPEP further states that the species claimed is anticipated when the species is clearly named within the prior art genus. Since the genus broadly disclosed by the Fodor *et al.* publication fails to call out any particular species of sequences, this reference does not anticipate the present claims.

Further, MPEP § 2131.03 states that a generic chemical formula will anticipate a claimed species covered by the formula only when the species can be “at once envisaged” from the formula. The generic formula set forth in the Fodor *et al.* publication (i.e., N1-N2-N3-N4-N5-N6-N7-N8-N9-N10-N11-N12-N13-N14-N15-N16-N17-N18-N19-N20-N21-N22-N23-N24-N25) would not permit a person having ordinary skill in the art to “at once envisage” the *PNMT* sequences recited in the present claims. Thus, the Fodor *et al.* publication does not anticipate the presently claimed nucleic acids.

In light of the above, Applicants respectfully request withdrawal of the rejection of claims 1, 8, and 38 under 35 U.S.C. §102(e).

The Examiner rejected claims 1 and 38-41 under 35 U.S.C. §102(e) as allegedly being anticipated by U.S. Patent No. 6,660,476 (the Comings *et al.* patent). The Examiner asserted that the Comings *et al.* patent teaches a *PNMT* polynucleotide having a G to A variant at positions 1303 and 1509 in present SEQ ID NO:1. The Examiner further alleged that the Comings *et al.* patent discloses molecular cloning and sequencing of *PNMT* alleles, thus anticipating claims 38-40. In addition, the Examiner alleged that the Comings *et al.* patent discloses the use of allele specific probes of about 30 nucleotides derived from *PNMT*, to be used for detection of variants, thus anticipating claim 41.

Applicants respectfully disagree. The present claims recite that the isolated nucleic acid molecule consists essentially of a nucleic acid sequence that is at least fifteen contiguous nucleotides of SEQ ID NO:6 or SEQ ID NO:1. As noted in the Preliminary Amendment filed on July 13, 2006, nucleic acid molecules “consisting essentially of” the recited sequences have the basic and novel characteristic that they are able to distinguish, based upon hybridization, a nucleic acid having a *PNMT* sequence that contains a variant from a nucleic acid having a sequence that does not contain the variant *PNMT* sequence. The sequence set forth in the Comings *et al.* patent that contains positions 1303 and 1509 of instant SEQ ID NO:1 is 4174 nucleotides in length. The sequence of Comings *et al.* would not distinguish, based upon hybridization, a nucleic acid having a *PNMT* sequence that contains a variant from a nucleic acid having a sequence that does not contain the variant *PNMT* sequence. Thus, this sequence does not consist essentially of a nucleic acid sequence that is at least fifteen contiguous nucleotides of

SEQ ID NO:1, as recited in the present claims. With respect to claims 38-41, the Comings *et al.* patent fails to disclose any nucleic acid molecule that is from 15 to 100 or from 20 to 50 nucleotides in length and consists essentially of a segment of SEQ ID NO:1 or SEQ ID NO:6, or any vector containing such a nucleic acid molecule. As such, the Comings *et al.* patent does not anticipate the present claims.

In light of the above, Applicants respectfully request withdrawal of the rejection of claims 1 and 38-41 under 35 U.S.C. §102(e).

The Examiner rejected claim 1 under 35 U.S.C. §102(b) as allegedly being anticipated by GenBank Accession No. AC079199.9. The Examiner stated that this reference discloses a polynucleotide sequence corresponding to a locus on *Homo sapiens* chromosome 17 that comprises a sequence encoding a human PNMT, and that shows a G to T mutation at position 12329, a position that corresponds to position 1102 of SEQ ID NO:1 as claimed in the instant application.

Applicants respectfully disagree. Again, the present claims recite that the isolated nucleic acid molecule consists essentially of a nucleic acid sequence that is at least fifteen contiguous nucleotides of SEQ ID NO:6 or SEQ ID NO:1. The sequence set forth in the GenBank Accession No. AC079199.9 is 161,815 nucleotides in length. Thus, this sequence does not consist essentially of a nucleic acid sequence that is at least fifteen contiguous nucleotides of SEQ ID NO:1, as recited in the present claims. As such, GenBank Accession No. AC079199.9 does not anticipate the present claims.

In light of the above, Applicants respectfully request withdrawal of this rejection of claim 1 under 35 U.S.C. §102(b).

The Examiner rejected claim 1 under 35 U.S.C. §102(b) as allegedly being anticipated by the Chin reference ("On the Preparation and Utilization of Isolated and Purified Oligonucleotides"). The Examiner asserted that the Chin reference discloses a 10-mer oligonucleotide sequence that includes a portion of present SEQ ID NO:1 with a G to A variant at the position corresponding to nucleotide 1509.

Applicants respectfully disagree. Simply writing out the sequences of all nucleic acids having selected lengths adds nothing to the prior art that wasn't already there, inherently or otherwise. Any person knowing the four-letter DNA alphabet, and instructed to write out every possible DNA sequence of a given length, could do so if given sufficient time. Using a computer program to generate such a listing does not change fundamental reality. One could envision a roomful of monkeys at keyboards having four keys – A, T, G, and C – generating random 20-mers for a selected period of time. A publication disclosing millions of such generated sequences, if held to be anticipatory, could prevent the relevant industries, as well as individual inventors, from protecting their valuable nucleic acid inventions. Such a policy would constitute a failure to promote the progress of science and the useful arts. U.S. CONST. art. I, § 8. Applicants further submit that absent the teachings presented in the instant specification, there would be no reason for a person of ordinary skill in the art to select, from the millions of generated sequences, the particular nucleotide sequences recited in the present claims. Thus, Applicants submit that the Chin reference does not anticipate the previous claims.

To further prosecution, however, the claims have been amended to recite that the isolated nucleic acid molecule consists essentially of a nucleic acid sequence that is at least fifteen contiguous nucleotides of SEQ ID NO:6 or SEQ ID NO:1. At no point does the Chin reference disclose such a nucleic acid. For example, the Chin reference fails to disclose any nucleic acid that is at least 15 nucleotides in length. Thus, this reference does not anticipate the present claims.

In light of the above, Applicants respectfully request withdrawal of this rejection of claim 1 under 35 U.S.C. §102(b).

Request for rejoinder

Applicants submit that claim 1 is allowable and is generic to the species of variants recited therein and in claims 3-10. Thus, Applicants respectfully request rejoinder and examination of all species recited in claims 1, 3-7, 9, and 10.

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Page : 12 of 12

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CONCLUSION

Applicants submit that claims 1, 3-12, and 38-41 are in condition for allowance, which action is respectfully requested. The Examiner is invited to telephone the undersigned agent if such would further prosecution.

Please apply any charges or credits to deposit account 06-1050.

Respectfully submitted,

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